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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,237	08/31/2001	Norikazu Nishino	08206-013001/PH-749PCT-US	2322

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EXAMINER	
LUKTON, DAVID	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/945,237	NISHINO ET AL.	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 8-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 8-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Pursuant to preliminary amendment, claims 6 and 7 have been canceled, claims 1-5, 8 amended, and claims 10-11 added. Claims 1-5, 8-11 are pending.

✧

This application contains at least one sequence disclosure that is encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can (continue to) be examined under 35 U.S.C. §131 and §132.

See the sequence on page 42, line 20.

Applicant is given the time period set in this Office action within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

✧

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 8-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the specification as filed, the claimed compound was described as a tetrapeptide that is "represented" by the indicated structural formulas. Now, claim 1 recites that the claimed compound "comprises" the indicated structural formulas. This constitutes new matter. The wording of claims 6 and 7 is noted. However, in these claims, the term "comprising" was used in conjunction with the phrase "an active ingredient". Furthermore, even in these two claims, the tetrapeptide derivative did not itself "comprise" anything. Claims 6 and 7 are interpreted to refer to compositions that comprise a compound of claim 1 (as claim 1 was originally filed), together with a second ingredient, such as a carrier. Similarly, the phrase at page 13, line 15+ does not support the amendment.

An issue separate from the foregoing concerns claim 10. This claim recites essentially (last line of the claim) that an inhibitor is inhibited. However, there does not appear to be descriptive support for inhibiting an inhibitor. Applicants are requested to point to the relevant page and line number.

✧

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 8 recites the term "pharmaceutical composition". The term "pharmaceutical" implies an assertion of therapeutic efficacy. The specification implies that the claimed compounds will be effective to treat cancer in patients afflicted with this disease. Claim 9 also asserts efficacy in this regard. What applicants have shown is that representative compounds of the invention can inhibit histone deacetylase *in vitro*, and that compounds of the invention can promote MHC class I molecule expression. Perhaps one can argue that if a compound is effective to inhibit histone deacetylase, and to promote MHC class I molecule expression, the compound will be effective to inhibit proliferation of tumor cells. However, even if true, a finding that the claimed compounds can inhibit proliferation of tumor cells would not be sufficient to enable a claim that is drawn to a method of treating cancer in humans, or to a claim that is drawn to a "pharmaceutical" composition.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988), the factors to consider in evaluating the need (or absence of need) for

"undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims. The following references discuss the matter of various attempts by oncologists to treat cancer: Viallet (*Lung Cancer* **15** (3) 367-73, 1996); Kemeny (*Seminars in Oncology* **21** (4 Suppl 7) 67-75, 1994); Newton (*Expert Opinion on Investigational Drugs* **9** (12) 2815-29, 2000); Giese (*Journal of Cancer Research and Clinical Oncology* **127** (4) 217-25, 2001); Garattini (*European Journal of Cancer* **37** Suppl 8 S128-47, 2001); Ragnhammar (*Acta Oncologica* **40** (2-3) 282-308, 2001). On a daily basis, numerous people die from cancer despite being administered compounds which have shown some promise in *in vitro* tests. The reality is that attempts to treat cancer using agents which have exhibited *in vitro* activity leads to "unpredictable" results. Accordingly, "undue experimentation" would be required to practice the invention of claims 8 and 9.

It is suggested that the term "pharmaceutical" be deleted wherever it occurs. It is also suggested that the term "anti-cancer" be deleted from claim 9. If deemed appropriate, the following claim can be added:

> *A composition comprising a pharmaceutically acceptable carrier in combination with the cyclic tetrapeptide derivative according to claim 1 in an amount effective to inhibit growth of tumor cells.*

✧

Claims 8-10 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 8 is drawn to a "composition", yet only one component is specified. A single pure compound is just that; a single pure compound is not a composition. A composition must have a second component, or else it is a compound. Thus, claim 8 mandates the presence of a second component, yet is silent as to what that second component might be. It is suggested that the second component be specified.

- Claim 10 recites essentially (last line of the claim) that an inhibitor is inhibited. What exactly does this mean?

❄

Reference "AB" (WO 00/52033) was stricken from the IDS because of the absence of a translation.

No claim is allowed.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at 571-272-0951. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.